

#### **COUNT IV**

##### **PURPORTED VIOLATIONS OF CONSUMER PROTECTION STATUTES**

629. Answering for paragraph 629, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 628. In addition, AstraZeneca admits that Plaintiffs purport to bring this Count to preserve their right to appeal, but denies that Plaintiffs may properly do so.

630. Admits that Plaintiffs purport to bring this Count on behalf of putative classes, but denies that Plaintiffs may properly bring this lawsuit as a class action as alleged in paragraph 630.

631. States that paragraph 631 consists of conclusions of law to which no response is required, except admits that Zeneca Inc. and AstraZeneca Pharmaceuticals LP are incorporated and have their principal place of business in Delaware, and that certain states have enacted consumer protection laws, but denies that AstraZeneca has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 631 as to the other parties.

632. States that paragraph 632 (and its subparts) consists of a conclusion of law to which no response is required, otherwise denies the allegations in paragraph 632 (and its subparts) to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any “AWP Scheme,” and further denies knowledge or information sufficient

to form a belief as to the truth of the allegations in paragraph 632 (and its subparts) as to the other parties.

633-635. Denies the allegations in paragraphs 633-635 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 633-635 as to the other parties.

636. States that paragraph 636 consists of a conclusion of law to which no response is required, otherwise denies the allegations in paragraph 636 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 636 as to the other parties. AstraZeneca further denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in paragraph 636.

## **COUNT V**

### **PURPORTED VIOLATIONS OF CONSUMER PROTECTION STATUTES: MEDICARE PART B CO-PAY "SUB-CLASS"**

637. Answering for paragraph 637, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 636. In addition, AstraZeneca admits that Plaintiffs purport to bring this Count in the alternative, but denies that Plaintiffs may properly do so.

638. Admits that Plaintiffs purport to bring this Count on behalf a nationwide class of persons who made a co-payment for a Part B covered drug manufactured by any defendant, but denies that Plaintiffs may properly bring this lawsuit as a class action as alleged in paragraph 638.

639. Admits that Plaintiffs propose as class representatives for purposes of this Count those persons named in paragraph 639, but denies that a class of Medicare Part B co-payors can be properly certified as alleged, and further denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 639 that the proposed representatives listed therein made co-payments based upon AWP for drugs manufactured by Track One Defendants, and that the proposed representatives have the same incentive as any Part B co-payor to represent this class.

640. Admits that Plaintiffs purport to seek certification of this class pursuant to Fed. R. Civ. P. 23(b)(3) for the damage claims and (b)(2) for the injunctive relief claims, but denies that such certification is appropriate.

641-642. Denies the allegations in paragraphs 641-642 (and its subparts) to the extent that they are directed at AstraZeneca and further denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 641-642 (and its subparts) as to the other parties. To the extent that paragraphs 641-642 (and its subparts) consist of conclusions of law, AstraZeneca states that no response is required.

643. States that paragraph 643 consists of conclusions of law to which no response is required and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 643.

644. States that paragraph 644 consists of conclusions of law to which no response is required and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 644. AstraZeneca further states that it received copies of letters dated October 6, 2005, purportedly directed to the Attorneys General of the States of

Utah, Louisiana, Illinois, Washington, Connecticut, Oregon, New Jersey, Missouri, Mississippi, and Kansas, that purport to give notice pursuant to Utah Code Ann. § 13-11-21(2), La. Rev. Stat. § 51:1409(B), 815 ILCS 505/10(a)(3)(d), Conn. Gen. Stat. § 42-100g(c), Wash. Rev. Code Ann. § 19.86.095, Or. Rev. Stat. § 646.638(2), N.J. Stat. Ann. § 56:8-20, Mo. Ann. Stat. § 407.025.7, Miss. Code Ann. § 75-24-15(2), and Kan. Stat. Ann. § 50-634(g).

## **COUNT VI**

### **PURPORTED VIOLATIONS OF CONSUMER PROTECTION STATUTES: THIRD-PARTY PAYORS PART B MEDIGAP “CLASS”**

645. Answering for paragraph 645, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 644. In addition, AstraZeneca admits that Plaintiffs purport to bring this Count in the alternative, but denies that Plaintiffs may properly do so.

646. Admits that Plaintiffs purport to bring this Count on behalf a nationwide class of third-party payors who made a payment for drugs covered by Medicare Part B, but denies that Plaintiffs may properly bring this lawsuit as a class action as alleged in paragraph 646.

647. Admits that Plaintiffs purport to seek certification of this class pursuant to Fed. R. Civ. P. 23(b)(3) for the damage claims and (b)(2) for the injunctive relief claims, but denies that such certification is appropriate.

648. Denies the allegations in paragraph 648 to the extent they are directed at AstraZeneca and further denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 648 as to the other parties. To the extent that paragraph 648 contains conclusions of law, AstraZeneca states that no response is required.

649. Denies the allegations in paragraph 649 (and its subparts) to the extent that they are directed at AstraZeneca and further denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 649 (and its subparts) as to the other parties. AstraZeneca further denies that Plaintiffs may properly bring this lawsuit as a class action under the state statutes alleged in paragraph 649. To the extent that paragraph 649 (and its subparts) contains conclusions of law, AstraZeneca states that no response is required.

650. States that paragraph 650 consists of conclusions of law to which no response is required and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 650.

651. States that paragraph 651 consists of conclusions of law to which no response is required and otherwise denies knowledge or information sufficient for form a belief as to the truth of the allegations in paragraph 651. AstraZeneca further states that it received copies of letters dated October 6, 2005, purportedly directed to the Attorneys General of the States of Utah, Louisiana, Illinois, Washington, Connecticut, Oregon, New Jersey, Missouri, Mississippi, and Kansas, that purport to give notice pursuant to Utah Code Ann. § 13-11-21(2), La. Rev. Stat. § 51:1409(B), 815 ILCS 505/10(a)(3)(d), Conn. Gen. Stat. § 42-100g(c), Wash. Rev. Code Ann. § 19.86.095, Or. Rev. Stat. § 646.638(2), N.J. Stat. Ann. § 56:8-20, Mo. Ann. Stat. § 407.025.7, Miss. Code Ann. § 75-24-15(2), and Kan. Stat. Ann. § 50-634(g).

**COUNT VII**

**PURPORTED VIOLATIONS OF CONSUMER PROTECTION STATUTES:  
PHYSICIAN-ADMINISTERED “CLASS” FOR CONSUMERS AND TPPS**

652. Answering for paragraph 652, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 651. In addition, AstraZeneca admits that Plaintiffs purport to bring this Count in the alternative, but denies that Plaintiffs may properly do so.

653. Admits that Plaintiffs purport to seek certification of this class pursuant to Fed. R. Civ. P. 23(b)(3) for the damage claims and (b)(2) for the injunctive relief claims, but denies that such certification is appropriate.

654. Admits that Plaintiffs propose as consumer class representatives for purposes of this Count and the Defendants indicated, those persons named in paragraph 654, but denies knowledge or information sufficient to form a belief that the purported representatives are appropriate representatives under Fed. R. Civ. P. 23.

655. Admits that Plaintiffs propose as third party payor class representatives for purposes of this Count those entities named in paragraph 655, but denies knowledge or information sufficient to form a belief that the purported representatives are appropriate representatives under Fed. R. Civ. P. 23.

656. Admits that Plaintiffs purport to seek certification of this subclass, but denies that such certification is appropriate.

657-658. Denies the allegations in paragraphs 657-658 (and subparts) to the extent that they are directed at AstraZeneca and further denies knowledge or information sufficient to form

a belief as to the truth of the allegations in paragraphs 657-658 (and subparts) as to the other parties. AstraZeneca further denies that Plaintiffs may properly bring this lawsuit as a class action under the state statutes alleged in paragraph 657-658. To the extent that paragraphs 657-658 (and subparts) consist of conclusions of law, AstraZeneca states that no response is required.

659. Denies the allegations in paragraph 659 to the extent that they are directed at AstraZeneca and further denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 659 as to the other parties.

## **COUNT IX**

### **ALLEGED CIVIL CONSPIRACY (AGAINST ALL DEFENDANTS)**

660. Answering for paragraph 660, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 659.

661. States that paragraph 661 consists of a conclusion of law to which no response is required, except admits that Plaintiffs purport to bring this Count on behalf of the AWP Payor Class, but denies that Plaintiffs may properly bring this lawsuit as a class action.

662-667. States that paragraphs 662-667 (and subparts) consist of conclusions of law to which no response is required, otherwise denies the allegations of paragraphs 662-667 (and subparts) to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any “AWP Scheme” or “Manufacturer-PBM Conspiracy,” as alleged in paragraphs 662 and 664, and denies knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 662-667 (and subparts) as to the other parties and

entities. AstraZeneca further denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in paragraph 667.

### **VIII. PRAYER FOR RELIEF**

AstraZeneca denies Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief, as stated in the unnumbered paragraph following paragraph 667 of the TAMCC.

### **DEFENSES**

Without assuming the burden of proof of such defenses that it would not otherwise have, AstraZeneca asserts the following defenses:

#### **First Defense**

Plaintiffs and the putative class fail to state a claim against AstraZeneca upon which relief may be granted.

#### **Second Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the political question and separation of powers doctrines.

#### **Third Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the filed rate doctrine.

#### **Fourth Defense**

Plaintiffs and the putative class have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of AstraZeneca as alleged in the TAMCC.



**Fifth Defense**

To the extent Plaintiffs and/or any member of the putative class obtain recovery in any other case predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against AstraZeneca based on the TAMCC pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

**Sixth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitutions of the States referenced in Counts IV, V, VI, and VII and any other States whose laws are or become relevant in the course of this multidistrict litigation.

**Seventh Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by AstraZeneca in judicial, legislative or administrative proceedings of any kind or at any level of government.

**Eighth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction or otherwise compromised their claims.

**Ninth Defense**

Any and all actions taken by AstraZeneca with respect to any of the matters alleged in the TAMCC were taken in good faith and in accordance with established industry practice.

**Tenth Defense**

Plaintiffs' and the putative class' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

**Eleventh Defense**

Plaintiffs' and the putative class' claims are preempted by the dormant Commerce Clause of the United States Constitution.

**Twelfth Defense**

Plaintiffs' and the putative class' claims against AstraZeneca are barred because AstraZeneca has complied with all applicable regulations of the federal and state governments.

**Thirteenth Defense**

Plaintiffs' and the putative class' claims against AstraZeneca are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

**Fourteenth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, because they violate AstraZeneca's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as all applicable state constitutions, insofar as Plaintiffs and the putative class members seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Fifteenth Defense**

AstraZeneca's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs or the putative class.

**Sixteenth Defense**

Plaintiffs and the putative class fail to state with particularity facts to support the fraud allegations, and fail to plead with particularity the fraudulent concealment and multi-source medicine allegations against AstraZeneca contained in the TAMCC.

**Seventeenth Defense**

Plaintiffs and the putative class fail to allege with particularity their civil conspiracy claims against AstraZeneca as required by Fed. R. Civ. P. 9(b).

**Eighteenth Defense**

Plaintiffs' and the putative class' claims against AstraZeneca are barred, in whole or in part, because AstraZeneca did not make any false statements to Plaintiffs or to any members of the putative class members. As to any statement asserted against AstraZeneca that Plaintiffs and the putative class allege to be false or misleading, AstraZeneca had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Nineteenth Defense**

Plaintiffs' and the putative class' claims against AstraZeneca are barred because AstraZeneca did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

**Twentieth Defense**

Plaintiffs' and the putative class' RICO claims against AstraZeneca are barred, in whole or in part, due to Plaintiffs' failure to properly allege a RICO enterprise as required by 18 U.S.C. § 1962(c).

**Twenty-First Defense**

Plaintiffs' and the putative class' RICO claims against AstraZeneca are barred, in whole or in part, due to their failure to plead facts showing that AstraZeneca and the PBMs are ongoing organizations whose members function as a continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981).

**Twenty-Second Defense**

Plaintiffs' and the putative class' RICO claims against AstraZeneca are barred, in whole or in part, due to their failure to allege that AstraZeneca conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).

**Twenty-Third Defense**

Plaintiffs and the putative class lack standing to bring their RICO claims against AstraZeneca because they cannot show that AstraZeneca directly caused their alleged injuries as required by 18 U.S.C. § 1964(c) and *Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992).

**Twenty-Fourth Defense**

Plaintiffs' and the putative class' civil conspiracy claims against AstraZeneca are barred, in whole or in part, by their failure to allege a concerted action as required by *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1564 (1st Cir. 1994) and *Grant v. John Hancock Mut. Life*

*Ins. Co.*, 183 F. Supp. 2d 344, 359 (D. Mass. 2002), and/or by their failure to allege a coercive conspiracy as required by *Fleming v. Dance*, 22 N.E.2d 609, 611 (Mass. 1939).

**Twenty-Fifth Defense**

Plaintiffs' and the putative class' civil conspiracy claims against AstraZeneca are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. *See Grant*, 183 F. Supp. 2d at 364.

**Twenty-Sixth Defense**

AstraZeneca denies that Plaintiffs and the putative class have valid consumer protection claims against AstraZeneca under the state statutes alleged in Counts IV, V, VI, and VII or any other State whose law is or becomes relevant in the course of this multidistrict litigation. However, if such claims are found to exist, AstraZeneca pleads all available defenses under the Acts.

**Twenty-Seventh Defense**

Any allegedly fraudulent statements or conduct of AstraZeneca did not directly or proximately cause the alleged injuries of Plaintiffs and/or any members of the putative class as required under the state statutes alleged in Counts IV, V, VI, and VII or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

**Twenty-Eighth Defense**

AstraZeneca's conduct was neither "deceptive," "misleading," "unlawful" nor "illegal" as required under the state statutes alleged in Counts IV, V, VI, and VII or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

**Twenty-Ninth Defense**

To the extent that Plaintiffs and the putative class members attempt to seek equitable relief against AstraZeneca, they are not entitled to such relief because they have an adequate remedy at law.

**Thirtieth Defense**

Plaintiffs and the putative class lack standing to bring their asserted consumer protection claims against AstraZeneca under the state statutes alleged in Counts IV, V, VI, and VII or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

**Thirty-First Defense**

Plaintiffs and the putative class did not rely on the allegedly fraudulent statements or conduct of AstraZeneca as required under certain state consumer protection laws, including without limitation those of New York and Pennsylvania.

**Thirty-Second Defense**

Any allegedly fraudulent statement or conduct of AstraZeneca was not consumer-oriented as required under certain consumer protection laws, including without limitation that of New York.

**Thirty-Third Defense**

Plaintiffs' and the putative class' claims against AstraZeneca for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Thirty-Fourth Defense**

Plaintiffs' and the putative class' claims for injunctive relief against AstraZeneca are barred by the doctrines of *in pari delicto* and/or unclean hands.

**Thirty-Fifth Defense**

This action cannot be maintained as a class action because (1) the certification and maintenance of this action as a class would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch; (2) the claims of Plaintiffs and the putative class cannot be properly joined with one another because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences; (3) the named Plaintiffs and the putative class cannot satisfy the procedural requirements of Fed. R. Civ. P. 23; (4) the questions of fact at issue are not common to the alleged class, but rather, are highly specific and will vary dramatically from person to person and entity to entity; and/or (5) class certification would violate AstraZeneca's rights provided by the Fifth, Seventh and Fourteenth Amendments to the United States Constitution as well as by the Constitutions of the States referenced in Counts IV, V, VI, and VII and any other States whose laws are or become relevant in the course of this multidistrict litigation, including but not limited to AstraZeneca's right to procedural and substantive safeguards, which include traditional defenses to liability.

**Thirty-Sixth Defense**

Plaintiffs' and the putative class' antitrust claims against AstraZeneca: (1) are barred because they have not suffered any antitrust injury; (2) are barred, in whole or in part, for lack of standing; and/or (3) should be dismissed because the alleged conspiracy does not make economic sense and is economically implausible.

**Thirty-Seventh Defense**

Any alleged restraints complained of in the TAMCC are ancillary to legitimate, procompetitive activity.

**Thirty-Eighth Defense**

AstraZeneca's conduct was not intended to have, did not have and was not likely to have had any adverse effects on competition in any relevant market.

**Thirty-Ninth Defense**

Plaintiffs' and the putative class' claims against AstraZeneca under Section 1 of the Sherman Act, 15 U.S.C. § 1, are barred to the extent recovery is based on indirect purchases of medicines.

**Fortieth Defense**

Plaintiffs' and the putative class' antitrust claims against AstraZeneca under the various state antitrust statutes are barred, in whole or in part, to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly interstate in nature.

**Forty-First Defense**

Plaintiffs' and the putative class' antitrust claims against AstraZeneca under the various state unfair trade and competition statutes are barred, in whole or in part, to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly intrastate in nature.

**Forty-Second Defense**

Plaintiffs' and the putative class' antitrust claims against AstraZeneca under the various state consumer protection and consumer fraud statutes are barred, in whole or in part, to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged



herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly intrastate in nature.

#### **Forty-Third Defense**

Plaintiffs' and the putative class' antitrust claims against AstraZeneca under the various state unfair trade, unfair competition, consumer protection and consumer fraud statutes are barred to the extent (1) those claims represent an impermissible circumvention of the states' antitrust statutes; and (2) those statutes apply only to deceptive or misleading conduct and/or govern only consumer transactions.

#### **Forty-Fourth Defense**

Third-party payor plaintiffs' and third-party payor putative class members' claims against AstraZeneca are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price on the ground that third-party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums, co-pays or other charges.

#### **Forty-Fifth Defense**

Plaintiffs' and the putative class' claims against AstraZeneca are barred, in whole or in part, with respect to any alleged overcharge or supracompetitive price because such supracompetitive price, if any, was absorbed, in whole or in part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members.

#### **Forty-Sixth Defense**

Plaintiffs' and the putative class' claims against AstraZeneca are barred, in whole or in part, due to their failure to join indispensable parties.

**Forty-Seventh Defense**

Plaintiffs' and the putative class' claims against AstraZeneca are barred, in whole or in part, because they have suffered no damages as a result of the matters alleged in the TAMCC.

**Forty-Eighth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties.

**Forty-Ninth Defense**

Plaintiffs' and the putative class' claims against AstraZeneca for damages are barred, in whole or in part, (1) because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to AstraZeneca; (2) because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the TAMCC; (3) by the doctrine of consent and/or ratification to the extent that Plaintiffs and/or putative class members have received and paid for medicines manufactured, marketed and sold by AstraZeneca after the filing of Plaintiffs' original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Fiftieth Defense**

AstraZeneca is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs and/or the putative class, with respect to the same alleged injuries.

**Fifty-First Defense**

Any damages recovered by the Plaintiffs and the putative class from AstraZeneca must be limited by the applicable statutory ceilings on recoverable damages.

**Fifty-Second Defense**

Plaintiffs and the putative class fail to allege facts or a cause of action against AstraZeneca sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

**Fifty-Third Defense**

To the extent punitive damages are sought, Plaintiffs' and the putative class' punitive damages claims against AstraZeneca: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the TAMCC are legally insufficient to support a claim for punitive damages against AstraZeneca; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give AstraZeneca prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of AstraZeneca's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the constitutions of any applicable states' laws; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and applicable states' laws; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against AstraZeneca for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of AstraZeneca's

medicines would constitute impermissible multiple punishments for the same wrong, in violation of AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law and statutory law of any applicable states' laws; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' law; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according AstraZeneca the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate AstraZeneca's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' laws.

#### **Fifty-Fourth Defense**

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against AstraZeneca cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive

damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of AstraZeneca; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiffs' and the putative class' burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate AstraZeneca's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law and public policies of any applicable states' laws.

#### **Fifty-Fifth Defense**

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against AstraZeneca cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate AstraZeneca's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate AstraZeneca's right not to be subjected to an excessive award; and (3) be improper under the constitutions, common law and public policies of any applicable states' laws.

**Fifty-Sixth Defense**

AstraZeneca adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

**Fifty-Seventh Defense**

AstraZeneca hereby gives notice that it intends to rely upon any other additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

AstraZeneca also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of any State whose law is or becomes relevant in the course of this multidistrict litigation.

WHEREFORE, AstraZeneca prays that this Court:

1. Dismiss the Third Amended Master Consolidated Class Action Complaint Amended to Comply with the Court's Class Certification Order with prejudice and enter judgment in favor of AstraZeneca against Plaintiffs;
2. Award AstraZeneca its costs and expenses; and

3. Grant such other and further relief for AstraZeneca as this Court deems just and proper.

November 3, 2005

/s/ Lucy Fowler  
Nicholas C. Theodorou, Esq. (BBO# 496730)  
Lucy Fowler (BBO # 647929)  
**FOLEY HOAG LLP**  
155 Seaport Boulevard  
Boston, MA 02210

D. Scott Wise, Esq. (admitted *pro hac vice*)  
Kimberley Harris, Esq. (admitted *pro hac vice*)  
**DAVIS POLK & WARDWELL**  
450 Lexington Avenue  
New York, NY 10017

ATTORNEYS FOR DEFENDANT  
ASTRAZENECA PHARMACEUTICALS LP

**CERTIFICATE OF SERVICE**

I certify that on November 3, 2005, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO 2, by causing a copy to be sent to Lexis/Nexis® File & Serve for posting and notification.

/s/ Lucy Fowler  
Lucy Fowler